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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| BINGHAM, MCCUTCHEN LLP THREE EMBARCADERO, SUITE 1800 SAN FRANCISCO, CA 94111-4067 | | | EXAMINER PANTUCK, BRADFORD C | |
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| | | | 3731 | |
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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/523,585

Applicant(s)

KEN ET AL.

Examiner

Bradford C Pantuck

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 February 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 32-41 and 43-46 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 32-41 and 43-46 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 10 March 2000 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____

DETAILED ACTION***Claim Rejections - 35 USC § 102***

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 32, 33, 35, and 39-41, and 43-46 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 5,354,295 to Guglielmi et al.

1. Regarding Claims 45 and 46, Guglielmi discloses in Fig. 3 a retainer deliverable via a tubular device (44) comprising a core wire (42) and a joint (54), which is electrolytically severable upon application of a current (col. 5, lines 44-47 and col. 6, lines 19-20). Joint 54, is made out of gold [Column 10, lines 65-67] and extends between the distal end of the core wire (46) and at least one array element (56) [see Fig. 4; Column 9, lines 12-17]. The joint (54) is a *soldered joint*—connecting the core wire (46) to an array element (56) [Column 9, lines 12-17]. Soldered joints are particularly susceptible to electrical currents (i.e. heat), and will dissolve after the application of current [Column 9, lines 56-64]. As this soldered joint (54) dissolves, core wire (46) will separate from array element (56), but inevitably some of the soldering material (gold) will remain on the core wire (56) and some will remain on array element (56). Thus, the *retainer assembly (46/54/56) will include a residual amount of the gold joint* after the electrolytic severance from the core wire.

Guglielmi discloses a vaso-occlusive device (58) [see Figures 3 and 4], which is a part of his retainer system. Applicant refers to vaso-occlusive devices as “useful in

filling vascular or other body spaces” [Specification, p. 1]. Vaso-occlusive device (58) takes up space within the aneurysm, as shown in Figure 4.

In Figures 7 and 8, the retainer assembly has a first shape when retained within the tubular device (col. 4, lines 33-37) and a second shape when retainer assembly is not retained in tubular device (col. 4, lines 44-46) wherein at least one array element extends outwardly from the joint in the second shape. In Fig. 5, the second shape is configured for retaining a vaso-occlusive device in an aneurysm. A coil can be introduced with devices such as the device of Guglielmi (see Abstract of U.S. Patent No. 5,639,277 to Mariani et al.).

2. Regarding Claim 32, Guglielmi discloses the core wire covered with an electrical insulation layer (col. 6, lines 20-21).
3. Regarding Claim 33, Guglielmi discloses at least one array element comprising platinum (col. 7, lines 55-60).
4. Regarding Claim 35, Guglielmi discloses at least one array element comprising stainless steel (col. 7, line 35).
5. Regarding Claim 39, Guglielmi discloses in Figure 4 that when the retainer assembly is in the second deployed shape, at least one array element terminates from the joint (54). In Figure 3, the array element (56) terminates at the joint.
6. Regarding Claims 40 and 41, Guglielmi discloses a retainer assembly (56/58) with a distal end (58) and a proximal end (proximal end of wire 56) [see Fig. 4]. That proximal end of wire (56) has a residual joint (54), as described above with reference to Claims 31 and 45. The residual joint (54) consists of a soldered metal, which will

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remain on the proximal end of retainer assembly (56/58) after breaking apart from core wire (46). The soldered metal will be both *distal to the proximal deployed end* and *on the proximal deployed end*, since it coats the proximal end and will extend somewhat up the proximal end of the wire.

7. Regarding Claim 43, Guglielmi discloses in Figures 4 and 5 the secondary deployed shape approximating the shape of a vascular aneurysm.
8. Regarding Claim 44, Guglielmi discloses in Figures 1A and 4 the retainer assembly enclosing a volume and wherein the retainer contains a helically wound vaso-occlusive device (col. 9, lines 21-23). A coil can also be introduced wherein the device of Guglielmi is capable of retaining the coil. It is well known to introduce coils with devices such as the device of Guglielmi et al. (see Abstract of U.S. Patent No. 5,639,277 to Mariant et al.).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 34 and 36-38 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,354,295 to Guglielmi et al. in view of U.S. Patent No. 5,639,277 to Mariant et al.

9. Regarding Claims 34, 37, and 38, Guglielmi discloses an implantable retainer but does not disclose at least one array element comprising tantalum. Mariant et al., however, disclose an analogous device using a radio-opaque material such as tantalum (col. 1, lines 53-55; col. 4, lines 13-18) in its composition. The use of tantalum is advantageous because of its radio-paque property, which allows one to observe and monitor the device's position [Column 3, line 67 to Column 4, line 2]. Guglielmi teaches putting the radio-opaque material inside of the device and *covering the device with the radio-opaque material* [Column 4, lines 13-18]. It is well known to make intra-venous catheters and implants out of radio-paque material (or to coat the device with such a material) for observation and would have been obvious to one of ordinary skill in the art at the time of the invention to make an array element of Guglielmi et al. out of a radio-opaque material, such as tantalum, as taught by Mariant et al. because this allows the array element to be supervised from outside the body.
10. Regarding Claim 36, Guglielmi discloses an implantable retainer, but does not disclose at least one array element comprising a super-elastic alloy. Mariant, however, discloses an analogous device comprised of a variety of materials. In Column 3, lines 66-67 and Column 4, lines 1-3 and 13-15, Mariant discloses alloys and elastic polymers such as polyethylene as being suitable materials for composing an array element. These materials are advantageous because they are biocompatible and flexible, which are both necessary for forming a vaso-occlusion. It is well known to compose an array element used in a blood vessel of a super-elastic alloy and would

have been obvious to one of ordinary skill in the art at the time of the invention to compose the array element of Guglielmi from a super-elastic alloy as in Mariant so that the array element would better conform to the vessel and be biocompatible.

Response to Arguments

11. Applicant's arguments filed January 20, 2004 have been fully considered but they are not persuasive. Regarding Applicant's assertion that Guglielmi does not disclose a "vaso-occlusive" system, Examiner disagrees. Guglielmi's apparatus will both partially *block the entrance to the opening* of the aneurysm (64) and *take up space* therein. Thus, his invention occludes a part of a blood vessel, i.e. is "vaso-occlusive."

Regarding Applicant's assertion that Guglielmi's retainer assembly (58, 56, 54) are not retained within the aneurysm, Examiner disagrees. Figure 5, particularly, shows an embodiment in which the retainer assembly retains the coil in the aneurysm (64). Column 9, lines 56-65 explain that a thrombus (74) is formed by Guglielmi's vaso-occlusive device, which *additionally* occludes the opening of the aneurysm and retains the assembly (58, 56, 54) therein.

Regarding Applicant's assertion that tip (58) is not capable of occluding (blocking/taking up space), Examiner disagrees. Tip (58) is shown in the drawings as a small ball on the distal end of array element (56), and is described as such in Column 9, lines 26-29. Tip (58) is described therein as being very similar to the tips (30 & 40) in Figures 1 and 2 respectively, which are very clearly separate, distinct

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components of the apparatus. Tip (58) is described throughout the patent description as being a *separate element* from the array (56).


Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bradford C Pantuck whose telephone number is (703) 305-8621. The examiner can normally be reached on M-F 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael J Milano can be reached on (703) 308-2496. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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March 1, 2004


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